



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

SUMMARY RECORD OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

Held in Brussels on 16th December 2008

(Section Genetically Modified Food & Feed and Environmental Risk)

Chair: Ms Dorothée André

All the Member States were present.

SECTION A - Information and/or discussion:

1. Review of the emergency measures on LLRice 601

A presentation was made of the final US Rice industry sampling and analysis data for the 2008 harvest. These data showed nearly all test results to be negative for the presence of LLRICE 601.

The Commission indicated that it would continue to reflect on the emergency measures taking account of the following:

- Data supplied by the US Rice industry,
- The findings and conclusions of the FVO report 2008-7857 concerning the evaluation of control activities in the USA regarding emergency measures for rice exports to the EU were presented to the Committee¹,
- Related alerts which have been issued in the previous 12 months through the Rapid Alert System for Food and Feed.

2. State of play on technical solution for the issue of Low Level Presence in the feed sector

The technical points of a proposal for harmonised controls on unauthorised GMOs were presented to the Members of the Committee. It was explained that the proposal, which is currently being discussed at interservice level, aims at harmonising the methods of sampling and analysis, performance criteria, and the rules for the interpretation of laboratory results for the detection of non-authorised GMOs and that it would be drafted within the current legal framework.

¹ http://ec.europa.eu/food/fvo/ir_search_en.cfm

The Commission explained that it was envisaged that the harmonised measure would contain technical annexes in two parts, the first relating to the method by which samples would be officially taken and secondly the methods by which these samples would be analysed and the results interpreted. On the first point it was indicated that the sampling would be based on the relevant aspects of existing sampling procedures contained in Commission Recommendation (EC) No 787/2004. On the second point it was stated that the quantitative approach was being discussed as a method of analysis for those GMOs for which an application has been made under Regulation (EC) No 1829/2003 and for which a validated method and appropriate control material is available from the Community Reference Laboratory.

In dealing with the technical constraints that are intrinsically linked with the method of analysis, a Minimum Required Performance Limit (MRPL) of 0.1% is being considered. This level is based on the fact that this is the minimum criterion for validating a method by the Community Reference Laboratory and corresponds to the lowest level where results are satisfactorily reproducible between official laboratories.

The Member States who expressed themselves welcomed the above mentioned initiative addressing important technical aspects as regards Low Level Presence. Several Members indicated that the scope of the measure should be widened to include food so as to better reflect the interrelationships of the food and feed chains, while one MS took an opposite view.

3. Evaluation of the legislative framework in the field of GM food and feed

The Commission presented the evaluation exercise of the legislative framework in the field of GM food and feed that it is planning to launch in 2009.

It was explained that the objective of the evaluation is to analyse the EU legislative framework on GM food and feed.

The Commission presented in synthesis the terms of reference of the evaluation, which will guide the external evaluator through the assessment of the legislative framework. The evaluation shall encompass the timeframe since the entry into force of Regulation (EC) No 1829/2003 and cover the 27 Member States of the European Union, although specific case studies might be considered in order to take into account the regional specifics resulting from cultural, traditional or organisational differences.

The assignment will be carried out in close co-operation with a Steering Committee composed by all the DGs and services participating in the EU GMO policy-making as well as by the European Food Safety Authority for the issues directly related to its competence as risk assessor.

Member States, stakeholders and interest groups will be involved in the process of evaluation through appropriate consultations.

The Commission made clear that continuous information will be provided to Member States through the meeting of the SCFCAH and that all the relevant information will be uploaded on the SANCO website. Member States were also informed that a similar exercise is being launched by DG ENV for the aspects dealing with the cultivation of GMOs.

4. Review of the emergency measure on Bt 63 rice

Updating the Member States on the implementation of Decision 2008/289/EC on emergency measures regarding the non-authorized genetically modified organism "BT 63" in rice products, the Commission informed that since 10 October 2008 no rapid alerts have been received.

Member States were also informed of the latest contacts with the Chinese competent authorities, in the context of two meetings held in Brussels with representatives of the Ministry of Agriculture and representatives of the Authority for Inspection and Quarantine (AQSIQ) respectively. In both occasions, the implementation of Decision 2008/289/EC was discussed and the Chinese competent authorities were informed about the elements of the implementation still to be improved.

The Commission also informed the Member States about the preliminary findings of the control mission of the Food and Veterinary Office (FVO) in China held between the 25th of November and the 4th of December. According to the Commission's internal procedures, the FVO is now analysing the data collected in order to prepare the draft report, this will then be submitted to the Chinese authorities for comments and then finalised and presented to the SCFCAH.

Findings are of such a nature that they do not necessitate immediate action on the Commission side. Against the presented background it was agreed to maintain in place the existing measure and wait until the finalisation of the FVO report for the next review.

In the meanwhile Member States were invited to pursue their control activities.

Miscellaneous

Study: Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice. A Leimirov et al. (2007)

The outcome of a study entitled "Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice" was made public on 11 November 2008 by the Austrian Federal Ministry of Health, Family and Youth. It has been erroneously reported in the media as indicating that NK603xMON810 maize had negative effects on mice reproduction.

A representative of Austria explained that this study was part of a global effort made by the Austrian government since more than ten years in relation to the safety of GMOs. As it was the case for previous studies of the same type, this study was not published in a peer-reviewed scientific journal but was made publicly available by the Austrian authorities and is intended to be published in a peer-reviewed scientific journal soon.

A representative of EFSA reported the conclusions of the review of this study that the GMO Panel carried out during its last meeting on 3-4 December 2008. The GMO Panel agreed that no conclusion could be drawn from the report since it contained some errors and inconsistencies and that important information was missing for a proper analysis of the data. The UK representative indicated that the competent UK scientific committee also considered this study and came to the same conclusion. EFSA also informed that, given the public attention to this report, the minutes of the

GMO Panel meeting on this point had been published on the EFSA website in advance of the complete minutes that are published after the next GMO Panel meeting.

A discussion took place where several delegations thanked EFSA for their analysis and regretted the misinformation of the public that was made on the basis of this report. Some delegations indicated that they had asked their scientific committee to further assess this study. In this regard, they indicated the need to have access to raw data possibly subject to confidentiality restrictions. It was also stressed that the use of non-standardised tests raises a number of issues for interpretation. Research studies for methodological purposes are not always suitable to draw conclusions on safety as such.

The chairman of the meeting concluded that there was a consensus within the committee that the present report does not question the safety of NK603xMON810 maize. Public communication on this type of study is important to avoid raising unfunded public concerns. It should be investigated by the Austrian authorities how they could provide the raw data (possibly with confidentiality status) to the other Member States and EFSA.

State of play of GM food/feed applications

- The Commission Decision on the authorisation of MON89788 soybean was adopted by the Commission on 4 December 2008².
- The proposal for a Council Decision for the authorisation of T45 oilseed rape was transmitted to the Council on 30th October 2008 and will be considered in the AGRI Council of January 2009.
- LLRice62 application: the Commission is currently working on a draft decision of authorisation.
- 59122xNK603 maize and MON89034 maize applications: the EFSA opinion on 59122xNK603 was published on 25th November 2008 on the EFSA website and the EFSA opinion on MON89034 will be published on 18th December 2008. In accordance with the legislation the public may submit comments on these opinions³.
- Mandate to EFSA for a consolidated opinion on the use of antibiotic resistance markers genes as marker gene in plants: EFSA has requested the extension of the deadline from 15th December 2008 to 31st March 2009 given the complexity of the topic and the time needed to adopt a co-opinion between 2 EFSA panels (GMO and BIOHAZ).

² Community register of genetically modified food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

³ http://ec.europa.eu/food/food/biotechnology/authorisation/public_comments_en.htm